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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/626,811	07/23/2003	Anthony David Auffret	PC25042A	2538

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PFIZER INC.
PATENT DEPARTMENT, MS8260-1611
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GROTON, CT 06340

EXAMINER	
HENRY, MICHAEL C	

ART UNIT	PAPER NUMBER
1623	

DATE MAILED: 10/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/626,811	AUFFRET ET AL.	
	Examiner	Art Unit	
	Michael C. Henry	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 May 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-29* is/are pending in the application.

4a) Of the above claim(s) *14-29* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The following office action is a responsive to the Amendment filed, 05/12/06.

The amendment filed 05/12/06 affects the application, 10/626,811 as follows:

1. Claims 1, 4, 5 have been amended. Claims 14-29 have been withdrawn

2. The responsive to applicants' arguments is contained herein below.

Claims 1-29 are pending in application

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The phrase "a form which gives a solution of relatively low viscosity that rapidly dissolves and disperses in the mouth of the consumer", in claim 1, renders the claim indefinite. More specifically, it is unclear how the solution can rapidly dissolve or dissolve when it is already a solution.

The term "relatively" in claim 1 renders the claim indefinite. More specifically, it is unclear what specific value of the low viscosity constitutes a "relatively" low value or amount and what specific value of the high viscosity constitutes a "relatively" high value or amount.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Mori et al. (DE 2737947, Abstract Only).

In claim 1, applicant claims "A process for preparing a dosage form, which affords a low viscosity solution when placed in the mouth of the consumer, which process comprises the steps of

(a) preparing a hydrated polymer composition comprising pullulan and sodium alginate having a relatively high viscosity suitable for casting;

(b) casting said composition into the shape of a dosage form; and

(c) drying said dosage form under such conditions as to provide a form which gives a solution of relatively low viscosity that rapidly dissolves and disperses in the mouth of the consumer."

Mori et al. disclose applicant's process for preparing a film comprising pullulan and sodium alginate, which process comprises (a) preparing a solution polymer composition comprising pullulan and sodium alginate having a viscosity suitable for casting; (b) casting said composition into the shape of a film (a dosage form); and (c) drying said film (dosage form) (see abstract). It should be noted that although Mori et al. is silent about the properties or characteristics of the form which pertains to its ability to rapidly dissolve and disperse in the mouth of a consumer, Mori et al.'s composition is the same as applicant's composition (which also comprises pullulan and sodium alginate) and is prepared by the same method, and consequently should inherently possess the same properties. Furthermore, it must be assumed

that since Mori et al. (like applicant) also casts their composition, then their composition must have a relatively high viscosity that is suitable for casting.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-6, 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leung et al. (WO 00/18365).

In claim 1, applicant claims "A process for preparing a dosage form, which affords a low viscosity solution when placed in the mouth of the consumer, which process comprises the steps of

(a) preparing a hydrated polymer composition comprising pullulan and sodium alginate having a relatively high viscosity suitable for casting;

(b) casting said composition into the shape of a dosage form; and

(c) drying said dosage form under such conditions as to provide a form which gives a solution of relatively low viscosity that rapidly dissolves and disperses in the mouth of the consumer." Dependent claims 2-6 are drawn to said method wherein the composition also comprises one or more pharmaceutically active agents and the composition is adjusted to specific pH range with specific acids. Dependent claim 8 is drawn to the process of claim 1 wherein the composition also contains one or both of the enzymes pullulanase and alginate lyase. Dependent claims 9 and 10 are drawn to the process of claim 1 wherein the composition or dosage form is

irradiated with gamma-radiation at specific amounts. Dependent claim 11 is drawn to said method dissolved solution has specific viscosity. Dependent claims 12 and 13 are drawn to said method wherein drying (step c) is carried out at specific temperature range for specific times periods.

Leung et al. disclose a process for preparing a physiologically consumable film (a dosage form), which process comprises the

(a) preparing a hydrated polymer composition comprising pullulan suitable for casting;

(b) casting said composition into the shape of a film (dosage form); and

(c) drying said dosage form to provide a form which dissolves in the mouth of a consumer (see examples, page 31, line 11 to page 31, line 12; see also claims 18, 29 and 30). In addition, Leung et al. disclose that their composition can contain mixtures of water soluble film formers such as pullulan and sodium alginate (see claim 29).

The difference between the applicant's claimed method and the method of Leung et al. is that Leung et al. do not specifically exemplify the use of sodium alginate together with pullulan in their preparation. However, Leung et al. disclose that their composition can contain mixtures of the water soluble film formers, pullulan and sodium alginate (see claim 29).

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made, to have used the method of Leung et al., to prepare a composition comprising pullulan and sodium alginate to be used for oral consumption, since Leung et al. disclose that pullulan and sodium alginate can be combined to form a physiologically consumable film.

One having ordinary skill in the art would have been motivated to have the method of Leung et al., to prepare a composition comprising pullulan and sodium alginate to be used for oral consumption, since Leung et al. disclose that pullulan and sodium alginate can be combined to form a physiologically consumable film. Dependent claims 2-6 which are drawn to said method wherein the composition also comprises one or more pharmaceutically active agents and the composition is adjusted to specific pH range with specific acids including aspartame, are also encompassed by this rejection since Leung et al. disclose the use of a pharmaceutically active agent (an antimicrobial) in the composition and disclose the use the aspartame in the composition (see claims and table 2, page 36). Furthermore, although Leung et al. do not disclose the pH of their composition, the adjustment of the pH is a matter of choice and does not appear to affect the composition formed. Dependent claim 8 which is drawn to the process of claim 1 wherein the composition also contains one or both of the enzymes pullulanase and alginate lyase, is also rejected as been obvious over Mori et al., since it is common and obvious to use or add enzymes that specifically catalyze the breakdown of substrates (such as pullulan and alignate) that are constituents of consumable compositions as to facilitate the digestion of said substrates. Dependent claims 9 and 10 which is drawn to the process of claim 1 wherein the composition or dosage form is irradiated with gamma-radiation at specific amounts, are also rejected as been obvious over Mori et al., since gamma irradiation is commonly applied in processing or sterilization of foods, consumables and the like.

Response to Arguments

Applicant's arguments with respect to claims 1-13 have been considered but are not found convincing.

The applicant argues that Mori et al. process is clearly not intended for the preparation of films for oral consumption. However, Mori et al. film is prepared comprising the same ingredients as applicant's composition (pullulan and sodium alginate). Mori et al. composition, like applicant's composition, is also casted and dried. Consequently, Mori et al. composition has a viscosity suitable for casting, since their composition (like applicant's composition) is also casted. Furthermore, although Mori et al. does not disclose that their films are intended for oral consumption, Mori et al. prepared film comprises the same ingredients as applicant's composition (pullulan and sodium alginate) and is not disclosed as having any physical characteristics such as quantity, size or weight that distinguishes it from applicant's film composition. Thus, Mori et al. composition should also rapidly dissolve and disperse in the mouth. In fact, Mori et al. composition is a composition that can be orally consumed, since both pullulan and sodium alginate are well known edible compounds.

The applicant argues that unlike Mori et aI., the film resulting from the first two steps according to the present invention is dried under such conditions so as to provide a film which gives a solution of lower viscosity than the original composition. This is not taught by Mori et al. wherein the cast composition is not placed in the mouth so no comparison of viscosity is possible. However, applicant's has not claimed any specific drying conditions that are different from Mori et al.'s drying conditions that would prevent Mori et al's composition or dosage form from producing a solution of relatively low viscosity. That is, both Mori et al. and applicant's composition are dried. Furthermore, applicant's claims are drawn to a process of preparing the said dosage form and applicant recites the same steps Mori et al. in the preparation of said

dosage form and consequently the dosage form produced should have the same reduced viscosity.

The applicant argues that while the composition of Leung et al. contains pullulan and sodium alginate, such composition does not undergo the vital third step of the present invention by which the viscosity of the cast composition is reduced to achieve rapid oral uptake. However, in the third step of both the applicant's and Leung et al.'s process the composition or dosage form is dried. Furthermore, applicant has not claimed or recited in the claims any specific drying condition that is not disclosed or suggested in Leung et al's process and is unobvious over Leung's et al. process but is required to produce a composition or form of reduced viscosity and would consequently render applicant's process unobvious over Leung's et al.'s.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Henry whose telephone number is 571-272-0652. The examiner can normally be reached on 8.30am-5pm; Mon-Fri. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael C. Henry

10/13/06

Shaojia Anna Jiang, Ph.D.
Supervisory Patent Examiner
Art Unit 1623

October 6, 2006.